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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,054	08/30/2001	Seiichi Araki	109536-161	8743
23483	7590	03/02/2006	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP 60 STATE STREET BOSTON, MA 02109			WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Reissue Applications

Claims 1-54 are presented for examination.

The request for continued examination (RCE) filed December 28, 2005 has been received and entered.

The amendment filed December 28, 2005 proposes amendments to claims 9, 15, 18, 19, 25, 28, 29, 35, 38, 39, 44, 47, 48 and 52 that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

Allowable Subject Matter

Claims 1-8 are allowable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating infections caused by *Escherichia coli* in a patient with a composition comprising riboflavin and/or riboflavin derivative and one or more composition formulation additives selected from amoxicillin, water-soluble polymers of claim 16, soy bean lecithin or yolk lecithin, proline, and glutamine administered in a form of intramuscular injection at proportions 10, 30 and 100 mg/kg, does not reasonably provide enablement for treating all types of infections caused by Gram-negative or Gram-positive bacteria, viruses, fungi, and

parasites; the composition formulation additives such as other antibiotics (broad), other water-soluble polymers (broad), and other lecithins (broad); administered intravenously, subcutaneously or orally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of treating infections by administering to a patient in need of such treatment a composition comprising riboflavin and/or riboflavin derivative and one or more composition formulation additives selected from the group consisting of antibiotics, water-soluble polymers, lecithin, proline and glutamine.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the instant composition comprising riboflavin and/or riboflavin derivative and one or more composition formulation additives selected from the group consisting of antibiotics, water-soluble polymers, lecithin, proline and glutamine are effective in treating all types of infections, and administered intravenously, subcutaneously and orally.

The breadth of the claims

The claims are very broad and inclusive to all types of infections caused by bacteria, viruses, fungi and parasites. Claims are very broad and inclusive to all types of antibiotics, water-soluble polymers and lecithins.

The amount of direction or guidance provided and the presence or absence of working examples

Example 1 shows riboflavin intramuscularly injected in a mouse infection with the *Escherichia coli* bacteria in proportions of 10, 30 and 100 mg/kg.

Example 2 shows a composition comprising riboflavin, glutamine and proline intramuscularly injected in a mouse infected with *E. coli* bacteria in proportion of 10, 30 and 100 mg/kg.

Example 3 shows sodium riboflavin phosphate (a derivative), intramuscularly injected in a mouse infected with *E. coli* bacteria in proportion of 10, 30 and 100 mg/kg.

Example 4 shows a composition comprising sodium riboflavin phosphate and amoxicillin (antibiotic) intramuscularly injected in a mouse infected with *E. coli* bacteria in proportion of 10, 30 and 100 mg/kg.

Example 5 shows a composition comprising riboflavin, polyvinyl pyrrolidone and sodium carboxymethyl cellulose (water-soluble polymers) and soy-bean lecithin and yolk lecithin (lecithin) intramuscularly injected in a mouse infected with *E. coli* bacteria in proportion of 10, 30 and 100 mg/kg.

No examples showing the instant composition comprising riboflavin and/or riboflavin derivative one or more composition formulation additives selected from the group consisting of antibiotics, water-soluble polymers, lecithin, praline and glutamine are effective against infections caused by Gram-negative and Gram-positive bacteria, fungi, viruses, and parasites.

No examples showing the instant composition showing that all types of antibiotics can be used.

No examples showing the instant composition showing that all types of water-soluble polymers can be used.

No examples showing the instant composition showing all types of lecithin such as oatmeal, wheat germ or peanuts can be used.

No examples showing the instant composition can be administered intravenously, subcutaneously and orally.

The quantity of experimentation necessary

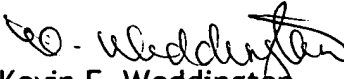
Applicants have failed to provide guidance as to how the treating all types of infections caused by Gram-negative or Gram-positive bacteria; viruses, fungi, and parasites; the composition formulation additives such as other antibiotics (broad), other water-soluble polymers (broad), and other lecithins (broad); administered intravenously, subcutaneously or orally. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 9-54 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Art Unit 1614

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February 13, 2006